K 021686

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AUG 2 0 2002

510(K) SUMMARY
Laser Fiber GF500

I. Submitter:

W.O.M. WORLD OF MEDICINE AG
Kaiserin-Augusta-Allee 113
10553 Berlin
Germany

II. Device Names:

1.	Classification Name:	Accessory to Laser Surgical Instrument
2.	Common or Usual Name:	Fiber Optic Delivery System
3.	Proprietary Name:	Laser Fiber GF500

III. Classification:

Class II in accordance with 21 C.F.R. § 878.4810. The product code for the device is GEX.

IV. Predicate Devices:

- **Laser Fiber GF100** (K011175), W.O.M. WORLD OF MEDICINE AG
- **InnovaQuartz General Shape Laser Fiber** (K994010) manufactured by InnovaQuartz, Inc.

V. Intended Use:

The Laser Fiber GF500 is intended to be used as a fiber optic delivery system in conjunction with the W.O.M. Laser U100 during lithotripsy procedures in the contact mode.

VI. Device Description:

The Laser Fiber GF500 is a disposable fiberoptic which is designed to deliver energy from the W.O.M. Laser U100 to the stone in lithotripsy. The fiber which is provided non-sterile is available in 3,5 and 5 meter in length.

VII. Substantial Equivalence:

The Laser Fiber GF500 described in this notification is similar in design, material and technological characteristics to the Laser Fiber GF100 (K011175) of W.O.M. WORLD OF MEDICINE AG and the InnovaQuartz General Shape Laser Fiber (K994010) manufactured by InnovaQuartz, Inc.

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All three devices are intended to be used as a fiber optic delivery system for ND:Yag laser systems. In addition, both the Laser Fiber GF500 and the predicate device Laser Fiber GF100 are designed for use in conjunction with the W.O.M. Laser U100 during lithotripsy procedures in the contact mode. Finally, both the proposed device and the InnovaQuartz General Shape Laser Fiber are approved for reuse.

The differences between the Laser Faser GF500 and predicate devices are minor and raise no new questions of safety and effectiveness. Accordingly, W.O.M. WORLD OF MEDICINE AG believes that the Laser Fiber GF500 is substantially equivalent to the predicate devices currently on the market.

VIII. Performance Data:

The device has been tested in accordance with the European Standard EN 554 and EN 1174. The Laser Fiber GF500 bears the CE mark in accordance with the Medical Device Directive 93/42/EEC.

Signed: S. Raab

Susanne Raab
Official Correspondent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2002

W.O.M. World of Medicine
c/o Susanne Raab
91 Trowbridge Street
Cambridge, Massachusetts 02138

Re: K021686
Trade/Device Name: Laser Fiber GF500
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: May 14, 2002
Received: May 22, 2002

Dear Ms. Raab:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

APPLICANT: WORLD OF MEDICINE Lemke GmbH

510(K) NUMBER (if known): K 021686

DEVICE NAME: Laser Fiber GF500

INDICATIONS FOR USE:

The Laser Fiber GF500 is intended to be used as a fiber optic delivery system in conjunction with the W.O.M. Laser U100 during lithotripsy procedures in the contact mode.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)

Prescription Use ✓ or Over-the Counter Use ——

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K02 1686